IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	David MacLean	
Serial No:	09/550,049	Art Unit: 3767
Filed:	April 14, 2000	Examiner: Gray, Phillip A.
For:	SAFETY DEVICE FOR USE WITH A VIAL	Attorney Docket: 0100/0091

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Smiths Medical ASD, Inc., which is the successor entity in interest of SIMS Portex Inc., to which the inventor assigned his interest per an Assignment recorded on April 14, 2000 with the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

Applications concurrently being appealed by the real party in interest are: application No. 09/920,860 appeal brief filed September 22, 2003 entitled "Needle Safety Device With Tortuous Path", application No. 09/962,240 appeal brief filed October 12, 2004 entitled "Needle Protection Device With Dampener", and application No. 10/925,962 appeal brief filed May 30, 2006 entitled "Needle Protection Device With Gauge Specific Color Coding And Method For Manufacturing Thereof". It is the belief of appellant that none of the noted appeals would directly affect or be directly affected by or have any bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-27 are in the application. Claims 7-21 were withdrawn from further consideration per an Office Action dated November 5, 2002.

Only claims 22-27 were appealed per an Appeal Brief filed on April 20, 2004 as claims 1-6 were allowed. A 1st request for re-instatement of the appeal was filed on February 11, 2005 in response to the reopening of the prosecution per an Office Action dated December 13, 2005. A 2nd request for re-instatement of the appeal was filed on March 22, 2005 in response to the re-opening of the prosecution per an Office Action dated March 7, 2005. A 3rd request for re-instatement of the appeal was filed on September 13, 2006 in response to the re-opening of the prosecution per an Office Action dated May 24, 2006 in which claims 1-6 were rejected along with claims 22-27.

Claims 1-6 were allowed and claims 22-27 have been rejected by the examiner per the latest Office Action dated December 18, 2006 once more re-opening the prosecution of this case.

The instant appeal brief is being filed to reinstate the appeal.

Claims 22-27, each having been rejected by the examiner, are hereby on appeal. The being appealed claims are listed in the attached Claims Appendix A.

For the convenience of the Board, allowed claims 1-6 and withdrawn claims 7-22 are listed in the attached Claims Appendix B.

STATUS OF AMENDMENTS

There was no amendment filed subsequent to the Office Action of December 18, 2006.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The instant invention, as set forth in independent claim 22, relates to a safety device (2) that comprises a collar (4), a neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar and a latch member (20) that extends from the neck in a direction towards the center of the collar. When the collar is placed about a vial (8) and moved towards a hub (28) of the vial until it is adjacent to one end of the hub, the latch member latches onto the other end of the hub [Figs. 1-8; page 5, line 15 to page 8, line 14].

Independent claim 25 recites a safety device that comprises a collar (4), a flexible neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar, and a latch member (20) that extends from the neck in a direction towards the center of the collar. For the invention set forth in the claim 25 embodiment, the latch member would continuously bias against the body of a vial (8) when the collar is placed about the vial and moved towards one end of the hub (28) of the vial. The latch member would latch onto another end of the hub when the collar is moved adjacent to the one end of the hub [Figs. 1-8; page 5, line 15 to page 8, line 14].

The instant invention is therefore directed to a safety device that has a collar that slidingly fits onto the body of a vial and is moved toward the hub of the vial, so that when the collar is adjacent to one end of the hub, the latch member at the neck that extends from the collar would latch onto the other end of the hub of the vial to thereby retain the collar to the vial. The housing that is attached to the other end of the neck away from the collar could then be pivoted to cover the needle that extends from the hub of the vial, per defined in claims 24 and 27.

The dependent claims that are discussed herein and which should be adjudged separately from the independent claims include claims 23 and 26.

Claims 23 and 26, dependent respectively from independet claims 22 and 25, each define the latch member (20) to be integrated to the neck (12) [extending from the collar (4)] and is flexible relative to the collar [Figs. 1-4; paragraph bridging pages 6 and 7].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 22-27 are anticipated by Mumford (US 6,575,941) under 35 U.S.C. 102(e)?

3. Whether claims 22 and 25 are anticipated by Olliffe (US 5,135,509) under 35 U.S.C. 102(b)?

ARGUMENT

1. Anticipation rejection of claims 22-27 under 35 U.S.C. 102(e) by Mumford (US 6,575,941)

"For a prior art reference to anticipate in terms of 35 U.S.C. 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Anticipation under 35 U.S.C. 102(e) requires that "`[e]ach and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference'". *In re Robertson*, 169 F.3d. 743, 746 (Fed. Cir. 1999).

Moreover, to anticipate a claim, MPEP 2131 states: "A claim is anticipated only if each and every element of the claim is found, either expressly or inherently described, in a single prior art reference.", and "The identical invention must be shown in as complete detail and is contained in the .... claim."

In rejecting claims 22-27 under 35 U.S.C. 102(b) as being anticipated by Mumford, the examiner relied upon Figures 8 and 9 of Mumford to show "a collar (lower portion of element 2 or 40), a neck (middle portion of element 2)", "a latch member (upper portion of element 2) integrated to neck and flexible relative to collar, wherein when said collar is placed about a vial (as in figure 1b) and moved toward hub (110) of said vial (114) said latch member is latched onto another end of the hub (as in figure 1b)." [Pages 3-4 of the Office Action dated December 18, 2006.]

As was pointed out above in the Summary of Invention section, each of claims 22 and 25 recites a collar, a neck extending from the collar, a housing pivotably connected to the end of the neck away from the collar, and a latch member extending from the neck in a direction towards the center of the collar. Moreover, claim 22 recites "wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub", and claim 25 recites "said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one end of said

hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub".

Mumford does not disclose anything close to the safety device set forth in independent claims 22 and 25. In particular, Mumford fails to disclose a collar "placed about a vial and moved toward one end of the hub of the vial". Nor does Mumford disclose any "neck" extending from the collar, or "any latch member extending from the neck in a direction to the center of the collar" as required in the claims.

To elaborate, Figs. 8 and 9 relied upon by the examiner in fact show how base 2 (Fig. 1A) is fabricated (column 12, lines 8-19). Fig. 8 is an embodiment of base 2 having a hollow interior, designated by 40, that increases air circulation during the manufacturing process to relieve pressure that otherwise builds up in the interior of base 2 during fabrication thereof, and also during the manufacturing process that adds the needle device shown in Fig. 7 to base 2 (column 12, lines 20-36). The final product is best shown in Fig. 1A, where the device is used with a syringe 10 by its luer end 9 (Fig. 1A and Fig. 7) being mated to the luer end 1 of syringe 10, and, as shown in Fig. 1B, where the device is used as a double-ended Vacutainer needle assembly.

Thus, the "collar" that the examiner pointed out in Mumford in fact is a hole through which the hub (wall 32 shown in Fig. 7) is inserted into, so that the needle 22 (Fig. 7) would extend through the top opening during the manufacturing process of the Mumford device. The complete device is shown in Fig. 1A, which particularly shows luer 9 extending to the underside of base 2, and needle 5, along with its hub, extending from the top of base 2. There is therefore no collar in the Mumford device. That being the case, there likewise is no "neck" in the Mumford device, insofar as base 2 is either a solid device (Fig. 1A) or a hollow device (Fig. 8) during its fabrication process.

There is also no "latch member" present in the Mumford device, insofar as the only things present at base 2 are the side lugs 3 and the front lug 4. These lugs, all protrusions, are specifically used to ensure that housing 6, when pivoted to cover needle 5, would be held securely in the closed position. Lug 4 fits snugly into the side opening of housing 6, while the side lugs 3 are shaped such that they act as snap catches to catch the protrusions 16 at the base of housing 6, when housing 6 is placed in the closed position

(column 10, lines 13-35). There is therefore no latch member that extends from the neck in a direction towards the center of the collar shown in the Mumford device.

The examiner asserts that Fig. 1B shows a collar being placed about a vial, by referencing element 114 to be the vial and element 110 the hub to which the collar (presumably base 102) moves toward.

It is respectfully submitted that Fig. 1B of Mumford does not teach or show anything similar to the assertion made by the examiner. In fact, Fig. 1B shows a disassembled view of the Mumford device being used as a blood collection needle, i.e., a double-ended needle (column 9, lines 50-67). To that end, Mumford teaches that the cannula 105 and the needle seat (or needle hub) 110 are connected to the top and bottom, respectively, of base 102. Mumford further discloses that needle seat 110 has attached thereto "a blood collection needle that is enclosed within a rubber cover 112" (column 9, lines 61-63). The needle seat, with the needle and its rubber cover 112 attached thereto, is protected from being exposed by means of the lower cover 114 (column 9, lines 65-67). Therefore, in contrast to the assertion made by the examiner, Fig. 1B fails to show a collar, a latch member, or any vial. Indeed, Fig. 1B shows merely a double-ended needle that incorporates the Mumford base 102. And the "vial 114" alluded to by the examiner in fact is a cover that covers the rubber cover 112, which in turn covers the needle that inserts into a vaccum blood collection tube when the device is used to collect blood.

In sum, Mumford fails to disclose: (1) a vial, (2) a collar that slides over the vial, (3) a latch member extending from the neck member in a direction towards the center of the collar, and (4) when the collar placed about the vial is moved toward a hub [or one end of the hub] of the vial, the latch member would latch onto another end of the hub when the collar is adjacent to the one end of the hub. Nothing in Mumford therefore remotely discloses or suggests the claimed invention.

In view of the above, appellant respectfully submits that the anticipation rejection of being appealed claims 22-27 by Mumford is without merit and not sustainable.

2. Anticipation rejection of claims 22 and 25 under 35 U.S.C. 102(b) over Olliffe (US 5,135,509)

The examiner asserts that Olliffe teaches "... a safety device (as in figures [sic] 8c) comprising a collar (lower portion of element 8 surrounds hub), a neck (middle portion extending from element 9) extending from collar, a housing (7) pivotable connected to neck, a latch member (upper portion of element 8, below hub 25) integrated to neck and flexible relative to collar, wherein device is fully capable of the function of when said collar is placed about a vial and moved toward hub (toward bottom of figure 8c) said latch member is latched onto another end of the hub." [Page 4 of the Office Action dated December 18, 2006.]

Olliffe teaches a needle assembly that has a needle guard which is pivotable relative to the needle hub by the actuation of an extension arm. As shown in the embodiment of Figs. 1-5, the shroud 7 of the Olliffe device has an extension arm 8 and, due to the mating of trunnion 6 at needle hub or boss 2 and hole 13 (Fig. 5A) at shroud 7, shroud 7 is movably fitted to needle hub 2. As shown in Fig. 2, shroud 7 may be moved to the opened position (dotted line) and to the closed position, by moving extension arm 8 (column 2, lines 24-28).

For the embodiment shown in Fig. 8 which the examiner relies upon, the operation is somewhat different. There the way in which shroud 7 covers needle 1 is by pressing extended arm 8 downwards, per illustrated by Figs. 8D-8G (column 4, lines 15-17). This is due to the forked portion 33 being resiliently connected to sleeve 21 by a hinge 32. Thus, when shroud 7 is in the open position (Fig. 8c), forked portion 33 would lie on shoulder 34 of the needle hub, as it is held in place by its two side ears 35 frictionally grasping sleeve 21. When arm 8 is forced downwards along needle hub 25, shroud 7 would snap to the closed position as arm 8, with its sleeve 21 embracing needle hub 25, is moved to the lowermost position along needle hub or needle boss 25 (column 4, lines 5-13).

Thus, Olliffe fails to disclose any latch member that extends from the neck in the direction to the center of the collar, or that the collar is placed about a vial and moved toward a hub of the vial. The best that could be argued with respect to Olliffe is that sleeve 21 fits about a needle hub. There is no vial disclosed anywhere in Olliffe. If anything, Olliffe clearly discloses that his device is to be used with a syringe barrel (column 2, lines 10-13). Nor could it be argued that the ears 35 that are a part of shroud 7 be considered as a latch member that latches onto another end of the hub when the collar is moved

toward the hub of a vial, for those ears 35 are used only when shroud 7 is in the open position as shown in Fig. 8C whereby the ears 35 act to hold shroud 7 at that position by frictionally fitting over sleeve 21 (column 4, lines 5-8). Thus, even assuming that ears 35 are latch members, the simple fact is that these "latch members" do not latch onto any portion of the hub when the collar is moved or when the shroud 7 covers the needle. Rather, as shown in Figs. 8G and 8A, when sleeve 21, by means of downward pressure on arm 8, is moved to the lowermost portion of needle hub 25, ears 35 would not hold onto anything other than being just the lower portion of shroud 7. There is therefore nothing in the Olliffe device that qualifies as a latch member that extends toward the center of a collar that would latch onto another end of the hub of a vial. Nor could element 33 of the Olliffe device be considered a latch, insofar as it is a forked portion that lies on the shoulder 34 of the needle hub 25, when shroud 7 is in the open position, per shown in Figs. 8C. As discussed above, it is the ears 35 being frictionally fitted over sleeve 21 that holds shroud 7 in the open position. And in contrast to the instant invention, when sleeve 21 is moved downwards along needle hub 25 to cause shroud 7 to cover needle 1, forked portion 33 would ride over shoulder 34 (column 4, lines 5-11). Thus, if anything, the movement of sleeve 21 causes fork portion 33 to move away from the needle hub.

In view of the foregoing, appellant respectfully submits that the anticipation rejection of being appealed claims 22 and 25 in view of Olliffe is without merit and not sustainable.

3. Conclusion

in view of the above, appellant respectfully submits that all grounds of rejection by the examiner are not sustainable and should be reversed.

Respectfully submitted,

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CLAIMS APPENDIX A

22. Safety device, comprising:
a collar;
a neck extending from said collar;
a housing pivotably connected to the end of said neck away from said collar; and
a latch member extending from said neck in a direction towards the center of said collar;
wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub.

23. Safety device of claim 22, wherein said latch member is integrated to said neck and flexible relative to said collar.

24. Safety device of claim 22,wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.

25. Safety device, comprising: a collar, a flexible neck extending from said collar, a housing pivotably connected to the end of said neck away from said collar, and a latch member extending from said neck in a direction towards the center of said collar, said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one end of said hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub.

26. Safety device of claim 25, wherein said latch member is integrated to said neck and flexible relative to said collar.

27. Safety device of claim 25, wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.

CLAIMS APPENDIX B

1. (Allowed) Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said hub having a shoulder and a base, said safety device comprising:

a collar slidably matable about said vial, said collar having a distal end;

a neck member extending from the distal end of said collar;

a housing pivotably connected to end of said neck member away from said collar; and

a latch member extending from said neck member in a direction towards center of said collar, said latch member coacting with the shoulder of said hub and the distal end of said collar coacting with the base of said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and the distal end of said collar is positioned adjacent said hub.

2. (Allowed) Safety device of claim 1, wherein said latch member is integrated to said neck member; and

wherein said neck member is flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

3. (Allowed) Safety device of claim 1, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent to said hub and said latch member is moved into position to latch onto a shoulder of said hub.

4. (Allowed) Safety device of claim 1, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

5. (Allowed) Safety device of claim 4, wherein said locking means comprises a hook integrated to interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

6. (Allowed) Safety device of claim 1, wherein said neck member comprises a flexible upright extending from said collar, and wherein said latch member comprises a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

7. (Withdrawn) Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said safety device comprising:

a collar slidably matable about said vial;

a support member extending from said collar;

a housing pivotably connected to the end of said support member away from said collar; and

a latch member extending from said collar in planar relationship with said support member, said latch member being flexible relative to said support member so as to coact with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved substantially adjacent to said hub.

8. (Withdrawn) Safety device of claim 7, wherein said support member comprises a frame extending from said collar and wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

9. (Withdrawn) Safety device of claim 7, wherein said support member is a rigid member and said latch member comprises a flexible upright extending from said collar and a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

10. (Withdrawn) Safety device of claim 7, wherein said latch member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said latch member latches onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said latch member from flexing away and disengaged from said hub.

11. (Withdrawn) Safety device of claim 10, wherein said locking means comprises a hook integrated to the interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

12. (Withdrawn) Safety device of claim 7, wherein said vial further comprises a gasket slidable along the length of said vial, said vial with said collar positioned adjacent said hub being placed into a cavity of a holder, said gasket being coupled to a plunger slidable along the length of said holder;

wherein fluid stored in said vial is ejected out of said vial through said needle when said plunger is pushed towards said hub.

13. (Withdrawn) In combination,

a collar slidably matable about a vial having a hub from which a needle extends;

a neck member extending from said collar;

a housing pivotably connected to the end of said neck member away from said collar,

a latch member positioned relative to said neck member coacting with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved to be substantially adjacent said hub; and

a holder having a cavity into which said vial having said collar mounted thereabout is fitted.

14. (Withdrawn) Combination of claim 13, wherein said latch member integrally extends from said neck member in a direction towards the center of said collar, said neck member being flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent said hub.

15. (Withdrawn) Combination of claim 13, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent said hub and said latch member is moved into position to latch onto a shoulder of said hub.

16. (Withdrawn) Combination of claim 13, wherein said neck member comprises a rigid support frame extending from said collar; and

wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

17. (Withdrawn) Combination of claim 13, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

18. (Withdrawn) Combination of claim 13, further comprising:

a gasket slidable along the length of said vial;

a plunger slidable along the length of said holder;

wherein said gasket is coupled to said plunger when said vial with said collar positioned adjacent said hub is fitted into said cavity of said holder so as to eject fluid stored in said vial through said needle when said plunger is pushed towards said hub.

19. (Withdrawn) Combination of claim 13, wherein said holder further comprises a turnable base member that, when rotated in one direction, would come into contact with the end of said vial away from said hub to thereby apply a biasing force against said vial to forcibly maintain said vial inside said cavity of said holder and said collar secured to said vial.

20. (Withdrawn) A method of attaching a needle protection housing to a vial, a hub formed at one end of said vial and a needle extending from said hub, comprising the steps of:

attaching said housing to a collar via a neck member;

extending from said neck member a latch member in a direction towards the center of said collar;

fitting said collar about said vial; and

moving said collar relative to said hub until said latch member latches onto a given portion of said hub to prevent said collar from moving away from said hub.

21. (Withdrawn) Method of claim 20, further comprising the steps of:

placing said vial fitted with said collar into a holder;

actuating a mechanism integral of said holder to apply a biasing force to said vial to securely retain said vial within said holder.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

CITATIONS